

Dockets **Management** Branch  
The Food and **Drug** Administration  
Department of Health & Human Services, **Rm. 1-23**  
12420 **Parklawn** Dr.  
**Rockville, MD 20857**

Date: 15 NOV 1999

Re: **99P-1340/CP 1** — Petition to Have **Eternity eau de parfum** declared "Misbranded"

Dear Sir or Madam:

5809 '99 NOV 29 A 9 56

In May 1999, the Environmental Health Network (EHN) submitted the above petition to have Calvin Klein's **Eternity eau de parfum** declared "misbranded." I am writing because I fully support this petition and request that the **FDA** give it careful attention with regard to your regulations **21CFR Sec. 740.1**, **21CFR Sec. 740.2**, and **21CFR Sec. 740.10**. Regulation **21CFR Sec. 740.10** states:

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

'Warning — The safety of this product has not been determined.'

As the petition shows, **Eternity** contains toxic ingredients and ingredients whose safety have not been substantiated. There is **no warning** label on its packaging.

We all have a right to know the status of safety testing of the ingredients in products such as **Eternity** so that we can protect ourselves and our families from toxic chemicals that may cause health problems. Most people are **not aware** that most fragrance materials have only limited safety testing. They wrongfully assume these products are safe to use in any setting and are surprised when people complain.

Like tobacco smoke, the harmful chemicals currently used in these products may affect the health of many people, including: people with asthma, chemical sensitivities, chronic fatigue, and other environmental illnesses. Children are particularly vulnerable to toxic chemicals found in products purchased and used by their parents, caregivers and teachers. When I am exposed to fragrance products I can experience any of the following symptoms based upon the chemical fragrance product I encounter:

- |  |   |  |  |
|--|---|--|--|
| 3 anaphylaxis/shock  | <input type="checkbox"/> double vision        | 3 incoherence  | <input type="checkbox"/> nausea                          |
| 3 anxiety, restlessness  | 3 ear pain                                    | 3 incontinence   | 3 nose bleeds  |
| 3 asthma   | 3 eczema                                      | 3 irritability   | 3 rashes   |
| 3 breathing difficulty   | 3 eyes, watery or dry                         | <input checked="" type="checkbox"/> joint aches          | <input checked="" type="checkbox"/> seizures             |
| <input type="checkbox"/> bronchitis  | 3 fatigue                                     | 3 laryngitis   | <input checked="" type="checkbox"/> short-term mem. loss |
| 3 can't concentrate  | 3 flushing                                    | 3 lethargy   | <input checked="" type="checkbox"/> sinusitis            |
| 3 coughing   | <input checked="" type="checkbox"/> headaches | 3 lymph nodes swell                                      | 3 sneezing   |
| <input type="checkbox"/> depression  | 3 heart beat irregularity                     | 3 mood swings  | 3 sores, skin /mouth                                     |
| <input checked="" type="checkbox"/> disorientation                         | <input type="checkbox"/> hives                | <input checked="" type="checkbox"/> muscle pain/weakness | <input type="checkbox"/> swallowing difficult            |
| <input type="checkbox"/> dizziness   | <input type="checkbox"/> hypertension         | 3 nasal congestion                                       | 3 tinnitus   |
| <input checked="" type="checkbox"/> other: <u>Complex Partial Seizures</u> |   |  |  |

Please act on behalf of the millions of people who have suffered physical illness and injury resulting from fragrance exposure at work, at school and in social settings. These toxic chemicals act as powerful barriers to people disabled by asthma and chemical sensitivities. Toxic chemicals in fragrances have already ruined countless lives. Thank you.

Sincerely,

R. Bruce McGeehan

your name

HC63 Box 7187 Snowflake AZ 85937

address, city / st / zip

99P-1340

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